

Message

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Subject: NEWS UPDATE: HHS Asks Court To Reject Industry Challenge To Styrene Cancer Listing (Risk Policy Report)

HHS Asks Court To Reject Industry Challenge To Styrene Cancer Listing

Posted: July 16, 2012

The Department of Health & Human Services (HHS) and parties intervening on its behalf in a case where industry challenges styrene's listing in the 12th Report on Carcinogens (RoC) are asking a federal judge to grant a summary judgment upholding the listing while denying industry's own recent request for a summary judgment overturning it.

Industry has argued that the styrene listing was arbitrary and capricious, made as a preordained conclusion that ignored negative evidence, and was based on some inaccurate information from staff in HHS' National Toxicology Program (NTP), which drafts the RoC monographs. Industry advocates have raised concerns about the styrene listing in the RoC because the document, while not regulatory in and of itself, can serve as the foundation for state and federal agencies such as EPA to issue regulations of the listed chemicals.

But in recent, separate June 29 briefs to the U.S. District Court for the District of Columbia, HHS and the Environmental Defense Fund, United Steelworkers and Chicago physician Peter Orris argue that the court, as a legal matter, can only rule on industry claims that the listing decision was "arbitrary and capricious" and that regardless the other arguments are not convincing anyway.

"In the end, the only issue properly before the Court is whether -- under the extremely deferential standard of review applicable to an agency's scientific judgments -- it was arbitrary and capricious for the Secretary to determine that styrene meets the listing criteria for a 'reasonably anticipated' human carcinogen," HHS writes in its filing. "[Health and Human Services Secretary Kathleen Sebelius'] decision clearly falls within the range of reasonable scientific judgment. The Court should therefore grant summary judgment to Defendants." *The filings are available on InsideEPA.com. (Doc ID: [2403956](#))*

The Styrene Information and Research Center (SIRC) filed a motion for summary judgment on May 18 as per a court-ordered schedule in *SIRC, et al. v. Sebelius et al.*, in which industry groups are challenging HHS' decision last summer to list styrene as "reasonably anticipated" to be a carcinogen.

Industry has argued that HHS' listing of styrene failed to meet standards outlined under the Information Quality Act (IQA) by not relying on strong enough science and not having a transparent enough process for public notice and comment. Industry argues the decision as a result was "arbitrary and capricious," in violation of the Administrative Procedure Act, which governs agency actions.

SIRC and other chemical industry groups have pushed HHS to speed up the implementation of a contract with the National Academy of Sciences (NAS) to review its RoC listings of styrene and formaldehyde as "reasonably anticipated" and "known" human carcinogens, respectively, as requested by Congress in language attached to HHS' fiscal year 2012 budget (*Risk Policy Report*, June 5). HHS' solicitation for the NAS peer review, which appeared on the Federal Business Opportunities website May 17, indicates the review is to be completed within 24 months of the award.

HHS, however, defends its actions, saying that industry is "invit[ing] the Court to substitute its own judgment for the agency's expert scientific judgment, which the Supreme Court and D.C. Circuit have expressly forbidden."

In their filings, HHS and the intervening parties argue industry cannot argue against the listing by saying staff gave Sebelius inaccurate information. Writing that "this attempted intrusion into the agency's deliberative process should be rejected out of hand," HHS says that "absent bad faith," courts cannot consider claims that staff prepared bad information and cannot "probe the mental processes of the Secretary."

Even if industry could argue on that point, HHS writes, the staff information was "entirely accurate and cast no doubt on the listing decision."

The defendants also argue industry's attempt to import an IQA claim into the case under the Administrative Procedure Act is invalid because IQA "commits actions to agency discretion, which precludes judicial review under the APA," the intervenors write.

HHS writes that "the IQA was satisfied in any event," as the seven-year listing process was supported in part by a background document that describes positive and negative evidence and references hundreds of scientific studies and reports.

Industry has not fared well in similar lawsuits over agencies' data, as judges have historically given significant leeway to agencies' scientific expertise and discretion. Judge Reggie Walton last June denied industry's motion for a preliminary injunction, though he also left the door open to additional briefing on the issue.

The styrene case then languished for months as the parties deadlocked over documents that industry requested but HHS argued were not required as part of the legal discovery process. In March, Walton issued a mixed ruling, requiring HHS to provide some but not all of the information that SIRC and Dart Container Corp. had sought. While his decision allowed industry to contest more of NTP's expert panels that created analyses of styrene for the RoC, his order says industry failed to prove grounds for considering NTP's independent analyses of the data (*Risk Policy Report*, April 10).

The RoC more generally has come under fire from a wide range of industry representatives and small business advocates who have argued the process that goes into drafting the RoC lacks transparency and does not have a strong enough weight-of-evidence approach. Those flaws, the industry stakeholders say, can result in unjustified carcinogen listings that policymakers can later use to justify regulations and that can create public stigma harming businesses using the substances.

Industry has expressed hope that NAS will, in addition to examining the styrene and formaldehyde listings, also take a broader look at the RoC listing process, much as another NAS panel did in an addendum to its landmark report that criticized EPA's formaldehyde carcinogen assessment in its Integrated Risk Information System.

HHS officials, Democrats and others have rejected industry's complaints as baseless and defended the RoC as scientifically and procedurally sound.

NTP Director Linda Birnbaum, also director of the National Institute of Environmental Health Sciences, where the interagency NTP is based, told a joint House subcommittee hearing April 25 that HHS hoped to have the contract in place with NAS by the end of fiscal year 2012, amid some small-business advocates' calls to consider whether to eliminate the RoC without significant reforms (*Risk Policy Report*, May 1).

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